

6113 W 230 350

BIOJECT INC.
7620 S W BRIDGEPORT ROAD
PORTLAND. OREGON 97224
TELEPHONE (503) 639-7221
FAX (503) 624-9002
WWW BIOJECT COM

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Dockets Management Branch [HFA-305] Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, Maryland 20852

RE: Docket No. 01P-0120; Medical Devices; Needle-Bearing Devices; Request for Comments and Information

To Whom It May Concern:

I am writing on behalf of Bioject, Inc.

Bioject, Inc., is a member of the National Alliance for the Primary Prevention of Sharps Injuries (NAPPSI). NAPPSI recently wrote a letter to FDA (dated August 27, 2002) requesting that FDA take the following three steps:

- 1. Publish NAPPSI's Notification to Clinicians on Sharps Injuries.
- 2. Disseminate information about NAPPSI's Safety Device List.
- 3. Involve NAPPSI in discussions aimed at creating a voluntary consensus standard for devices listed in the petition from the Service Employees International Union (SEIU) and Public Citizen's Health Research Group (HRG).

Bioject supports NAPPSI's request that FDA take the steps listed above.

Sincerely,

Nancy J. Gertlar

Director, Regulatory Affairs

Bioject, Inc.

cc: Timothy Ulatowski

**Brad Poulos** 



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